MAY 15 2009

FLOWCARDIA, INC.

4) 510(k) Summary

This summary of 510(k) information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21CFR807.92.

510(k) Number K091119

Applicant Information

Date Prepared: **April 16, 2009**

Name and Address: **FlowCardia, Inc.**
745 N. Pastoria Avenue
Sunnyvale, CA 94085
Ph: (408) 617-0352

Contact Person: **Dustin Michaels, Vice-President of CR/QA/RA**
Ph: (408) 617-0352 x302
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Device Information

Classification: DQY
Trade Name: The CROSSER System
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Device

The CROSSER System manufactured by FlowCardia, Inc. (K072776)

Device Description

The CROSSER® System consists of a re-usable electronic Generator, Foot Switch, high-frequency Transducer, and single-use CROSSER Catheter. The CROSSER Over the Wire Catheter is available in two variations:

- CROSSER 14P OTW (014 guidewire compatible flexible),
- CROSSER 14S OTW (014 guidewire compatible supportive).

Each Catheter is connected to the electronic Generator through the Transducer. The Foot Switch is used to activate the system. The Generator and Transducer convert AC power into high frequency mechanical vibrations which are propagated through a Nitinol core wire to the Titanium tip of the CROSSER Catheter. The main body of the catheter is constructed from Pebax and a hydrophilic coating which covers the distal end of the catheter.

Indications for Use

The CROSSER® System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries.

The CROSSER® Catheter is only intended for use with the CROSSER Electronics System. Refer to the CROSSER Electronics System Manual of Operations for proper use.

Technological Characteristics

The FlowCardia CROSSER Over the Wire Catheters are substantially equivalent to the predicate device. The predicate and CROSSER Over the Wire Catheters are identical with respect to indications for use and performance. The main difference is a rapid-exchange (RX) guidewire rail system in the predicate versus a conventional over-the-wire (OTW) guidewire rail system. With respect to materials and design, the CROSSER Over the Wire Catheters are substantially equivalent to the predicate device with the exception of the catheter effective length (140 vs. 146cm) and guidewire lumen materials.

Physical Test Data

Design analysis, bench, and biocompatibility testing were conducted according to the relevant guidance documents to demonstrate that the FlowCardia CROSSER Over the Wire Catheters met the acceptance criteria and performed similarly to the predicate device. In addition to dimensional verification, the following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence/Integrity, Bench top Simulated Efficiency, Catheter Fatigue Testing, Biocompatibility, and Shelf Life Testing.

Conclusion

Based upon the aforementioned comparison testing, the CROSSER Over the Wire Catheters are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FlowCardia, Inc.
Mr. Dustin Michaels
Vice President, Clinical, Quality & Regulatory Affairs
745 N. Pastoria Ave.
Sunnyvale, CA 94085

SEP 18 2013

Re: K091119
Trade/Device Name: The Crosser System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: April 16, 2009
Received: April 17, 2009

Dear Mr. Michaels:

This letter corrects our substantially equivalent letter of May 15, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

3) **Statement of Indications for Use**

510(k) Number (if known): K091119

Device Name: **The CROSSER® System**

Indications for Use:

The CROSSER® System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries.

The CROSSER® Catheter is only intended for use with the CROSSER Electronics System. Refer to the CROSSER Electronics System Manual of Operations for proper use.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K091119